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			03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/500.093 KHALAF ET AL. Office Action Summary Examiner Art Unit JULIE HA 1654 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 13 December 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 50-94 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) _____ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 50-94 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SZ/UE)
 Paper No(s)/Mail Date ______.

Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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DETAILED ACTION

The Restriction requirement mailed on June 13, 2007 inadvertently omitted election of species and claim 93. The Group restriction of Groups 1-169 is maintained and revised below to include claim 93. The election of species of the broad claims follows below.

Election/Restrictions

- Group restriction of Groups 1-169 are maintained as described in the previous office action.
- 2. Group 170, claim(s) 93, drawn to a method for the preparation of compound of N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]amino}carbonyl)-1-isopropyl-1-H-pyrrol-3-yl]-4-[(3,3-dimethylbutanoyl)amino]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]amino}carbonyl)-1-isopropyl-1-H-pyrrol-3-yl]-4-[(3,3-dimethylbutanoyl)amino]-1-methyl-1H-pyrrole-2-carboxamide.
- 3. Group 171, claim(s) 93, drawn to a method for the preparation of compound of N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]amino}carbonyl)-1-isopropyl-1-H-pyrrol-3-yl]-4-(formylamino)-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or

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(b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]amino}carbonyl)-1-isopropyl-1-H-pyrrol-3-yl]-4-(formylamino)-1-methyl-1H-pyrrole-2-carboxamide.

- 4. Group 172, claim(s) 93, drawn to a method for the preparation of compound of N-[3-(-(Dimethylamino)propyl]2-2({[4-{([4-(formylamino)-1-methyl-1H-pyrrol-2-yl]carbonyl]-amino)-5-isopropyl-1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[3-(-(Dimethylamino)propyl]2-2({[4-({[4-(formylamino)-1-methyl-1H-pyrrol-2-yl]carbonyl]-amino)-5-isopropyl-1,3-thiazole-4-carboxamide.
- 5. Group 173, claim(s) 93, drawn to a method for the preparation of compound of N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-isopropyl-1H-pyrrol-3-yl]-4-({[4-(formylamino)-1-isopropyl-1H-pyrrol-2-yl]carbonyl}-amino)-1-isopropyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-({[3-

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(Dimethylamino)propyl]amino}carbonyl)-1-isopropyl-1H-pyrrol-3-yl]-4-({[4-(formylamino)-1-isopropyl-1H-pyrrol-2-yl]carbonyl}-amino)-1-isopropyl-1H-pyrrole-2-carboxamide.

- 6. Group 174, claim(s) 93, drawn to a method for the preparation of compound of N-[5-({[3-([3-(Dimethylamino)propyl]amino}carbonyl)-1-isopentyl-1H-pyrrol-3-yl]amino}carbonyl)-1-isopentyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-({[3-([3-(Dimethylamino)propyl]amino}carbonyl)-1-isopentyl-1H-pyrrol-3-yl]amino}carbonyl)-1-isopentyl-1H-pyrrole-2-carboxamide.
- 7. Group 175, claim(s) 93, drawn to a method for the preparation of compound of N-[5-({[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-isopropyl-1H-pyrrol-3-yl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-(formyl-amino)-1-isopropyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-({[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-isopropyl-1H-pyrrol-3-yl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-(formyl-amino)-1-isopropyl-1H-pyrrole-2-carboxamide.

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8. Group 176, claim(s) 93, drawn to a method for the preparation of compound of N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]2-{{[4-(formylamino)-1-methyl-1H-pyrrol-2-yl]carbonyl}-amino)-5-isopropyl-1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-({[3-(Dimethylamino)propyl]amino}carbonyl)-1-methyl-1H-pyrrol-3-yl]2-({[4-(formylamino)-1-methyl-1H-pyrrol-2-yl]carbonyl}-amino)-5-isopropyl-1,3-thiazole-4-carboxamide.

- 9. Group 177, claim(s) 93, drawn to a method for the preparation of compound of 4-([[4-(Formylamino)-1-methyl-1-H-pyrrol-2-yl]carbonyl]amino)1-isopropyl-N-[1-methyl-5-([3-(4-morpholinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 4-{[[4-(Formylamino)-1-methyl-1-H-pyrrol-2-yl]carbonyl]amino)1-isopropyl-N-[1-methyl-5-{[3-(4-morpholinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]-1H-pyrrole-2-carboxamide.
- 10. Group 178, claim(s) 93, drawn to a method for the preparation of compound of 4-(Formylamino)-N-[1-isopropyl-5-([[1-methyl-5-([[3-(1-pyrrolidinyl)-propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a

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compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 4-(Formylamino)-N-[1-isopropyl-5-([[1-methyl-5-([[3-(1-pyrrolidinyl)-propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrole-2-carboxamide.

- 11. Group 179, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-(formylamino)-1-methyl-1- H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-(formylamino)-1-methyl-1- H-pyrrole-2-carboxamide.
- 12. Group 180, claim(s) 93, drawn to a method for the preparation of compound of 2-(Acetylamino)-N-[5-([[5-([[3-(dimethylamino)propyl]amino]-carbonyl)-1-m- ethyl-1H-pyrrol-3-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-5-isopropyl-1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 2-

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(Acetylamino)-N-[5-([[5-([[3-(dimethylamino)propyl]amino]-carbonyl)-1-m- ethyl-1H-pyrrol-3-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-5-isopropyl-1,3-thiazole-4-carboxamide.

- 13. Group 181, claim(s) 93, drawn to a method for the preparation of compound of 2-(Acetylamino)-N-[5-([[4-([[3-(dimethylamino)propyl]amino]-carbonyl)-5-i- sopropyl-1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 2-(Acetylamino)-N-[5-([[4-([[3-(dimethylamino)propyl]amino]-carbonyl)-5-i- sopropyl-1,3-thiazole-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-5-isopropyl-1,3-thiazole-4-carboxamide.
- 14. Group 182, claim(s) 93, drawn to a method for the preparation of compound of 2-(Acetylamino)-N-(5-[[(3-[[3-(dimethylamino)propyl]amino]-3-oxo-propyl)amino]carbonyl]-1-methyl-1H-pyrrol-3-yl)-5-isopropyl-1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 2-(Acetylamino)-N-(5-[[(3-[[3-(dimethylamino)propyl]amino]-3-oxo-propyl)amino]carbonyl]-1-methyl-1H-pyrrol-3-yl)-5-isopropyl-1,3-thiazole-4-carboxamide.

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- 15. Group 183, claim(s) 93, drawn to a method for the preparation of compound of N^1,N^3 -Bis(2-[[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)- -5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-amino]-2-oxoethyl)isophthalamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N^1,N^3 -Bis(2-[[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)- -5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-amino]-2-oxoethyl)isophthalamide.
- 16. Group 184, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopropyl-1H-pyrrol-3-yl]-4-(acetylamino)-1-methyl-1-H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[5-([[3-([Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopropyl-1H-pyrrol-3-yl]-4-(acetylamino)-1-methyl-1-H-pyrrole-2-carboxamide.
- 17. Group 185, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-(acetyl-amino)-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound

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of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-[[[5-([[3-([[3-([Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-(acetyl-amino)-1-methyl-1H-pyrrole-2-carboxamide.

- 18. Group 186, claim(s) 93, drawn to a method for the preparation of compound of N^2 , N^5 -Bis[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)-5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N^2 , N^5 -Bis[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)-5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide.
- 19. Group 187, claim(s) 93, drawn to a method for the preparation of compound of N^2,N^5 -Bis[1-isopentyl-5-([[1-methyl-5-([[3-(4-morpholinyl))propyl]-amino]carbonyl)-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N^2,N^5 -Bis[1-isopentyl-5-([[1-methyl-5-([[1-methyl-5-([1-methyl-5-

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methyl-5-([[3-(4-morpholinyl)propyl]-amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide.

- 20. Group 188, claim(s) 93, drawn to a method for the preparation of compound of N^2 , N^5 -Bis[5-([[5-([[3-(dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N^2 , N^5 -Bis[5-([[5-([[3-(dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide.
- 21. Group 189, claim(s) 93, drawn to a method for the preparation of compound of N^2 , N^5 -Bis[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)-propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N^2 , N^5 -Bis[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)-propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1H-indole-2,5-dicarboxamide.

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22. Group 190, claim(s) 93, drawn to a method for the preparation of compound of 2-([[4-([[4-(Acetylamino)-1-methyl-1H-imidazol-2-yl]carbonyl]-amino)-1-methyl-1H-pyrrol-2-yl]carbonyl]amino)-N-[3-(dimethylamino)-propyl]-5-isoprop-yl-1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 2-([[4-([[4-(Acetylamino)-1-methyl-1H-imidazol-2-yl]carbonyl]-amino)-1-methyl-1H-pyrrol-2-yl]carbonyl]amino)-N-[3-(dimethylamino)-propyl]-5-isoprop-yl-1,3-thiazole-4-carboxamide.

- 23. Group 191, claim(s) 93, drawn to a method for the preparation of compound of 4-(Acetylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl) propyl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 4-(Acetylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl) propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrol-2-carboxamide.
- Group 192, claim(s) 93, drawn to a method for the preparation of compound of N-[1-Isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)-propyl]amino-]carbonyl)-1H-

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pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-4-[(3-methoxybenzoyl)amino]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[1-Isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)-propyl]amino-]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-4-[(3-methoxybenzoyl)amino]-1-methyl-1H-pyrrole-2-carboxamide.

- 25. Group 193, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-([[5-(formylamino)-2-methyl-3-thienyl]carbonyl]amino)-1-isopentyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-([[5-(formylamino)-2-methyl-3-thienyl]carbonyl]amino)-1-isopentyl-1H-pyrrole-2-carboxamide.
- 26. Group 194, claim(s) 93, drawn to a method for the preparation of compound of N[5-([[5-([[3-(dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-5-isopropyl-2-[(3-methoxybenzoyl)amino]1,3-thiazole-4-carboxamide which comprises: (a) reaction of compound of formula III
 with a compound of formula (IV), or (b) for compounds of formula I in which R1

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represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[5-([[3-(dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-5-isopropyl-2-[(3-methoxybenzoyl)amino]-1.3-thiazole-4-carboxamide.

- 27. Group 195, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-[[(5-[[(9,10-dioxo-9,10-dihydro-2-anthracenyl)carbonyl]-amino]-2-methyl-- 3-thienyl)carbonyl]amino]-1-isopentyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-[[(5-[[(9,10-dioxo-9,10-dihydro-2-anthracenyl)carbonyl]-amino]-2-methyl-- 3-thienyl)carbonyl]amino]-1-isopentyl-1H-pyrrole-2-carboxamide.
- 28. Group 196, claim(s) 93, drawn to a method for the preparation of compound of N[1-(Cyclopropylmethyl)-5-([[5-([[3-(dimethylamino)propyl]-amino]carbonyl)-1-methyl-1Hpyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-4-(formylamino)-1-methyl-1H-pyrrole-2carboxamide which comprises: (a) reaction of compound of formula III with a compound
 of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]nC(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound

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of formula VI, or (c) deprotection of a protected derivative of a compound N-[1-(Cyclopropylmethyl)-5-([[5-([[3-(dimethylamino)propyl]-amino]carbonyl)-1-methyl-1Hpyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-4-(formylamino)-1-methyl-1H-pyrrole-2carboxamide.

- 29. Group 197, claim(s) 93, drawn to a method for the preparation of compound of 1-Cyclopentyl-N-[5-([[3-(dimethylamino)propyl]amino]carbonyl)-1-methyl-1H--pyrrol-3-yl]-4-([[4-(formylamino)-1-methyl-1H-pyrrol-2-yl]-carbonyl]-amino)-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 1-Cyclopentyl-N-[5-([[3-(dimethylamino)propyl]amino]carbonyl)-1-methyl-1H--pyrrol-3-yl]-4-([[4-(formylamino)-1-methyl-1H-pyrrol-2-yl]-carbonyl]-amino)-1H-pyrrole-2-carboxamide.
- $\label{eq:compound} 30. \qquad \text{Group 198, claim(s) 93, drawn to a method for the preparation of compound of N^2,N^7-Bis[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)-5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-9,10-dihydro-2,7-$

phenanthrenedicarboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N²,N⁷-Bis[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)-5-isopropyl-

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1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-9,10-dihydro-2,7-phenanthrenedicarboxamide.

- 31. Group 199, claim(s) 93, drawn to a method for the preparation of compound of 4-(Formylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 4-(Formylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrole-2-carboxamide.
- 32. Group 200, claim(s) 93, drawn to a method for the preparation of compound of 4-(Acetylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-morpholinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1-H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 4-(Acetylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-morpholinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1-H-pyrrole-2-carboxamide.

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33. Group 200, claim(s) 93, drawn to a method for the preparation of compound of 4-(Formylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-

(rormylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-morpholinyl))propyl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1-H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound 4-(Formylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-morpholinyl)propyl]amino]carbonyl)-1H-pyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1-H-pyrrol-2-carboxamide.

- 34. Group 201, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-[(3-methoxybenzoyl)amino]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-4-[(3-methoxybenzoyl)amino]-1-methyl-1H-pyrrol-2-carboxamide.
- Group 202, claim(s) 93, drawn to a method for the preparation of compound of N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-

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yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-[[(4-methoxyphenyl)acetyl]amino]-1-methyl-1H-pyrrole-2-carboxamide which comprises: (a) reaction of compound of formula III with a compound of formula (IV), or (b) for compounds of formula I in which R1 represents D-A-N(H)-[Q]n-C(O)-E-C(O)-, reaction of two equivalents of a compound of formula V with a compound of formula VI, or (c) deprotection of a protected derivative of a compound N-[5-([[5-([[3-(Dimethylamino)propyl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]amino]carbonyl)-1-isopentyl-1H-pyrrol-3-yl]-4-[[(4-methoxyphenyl)acetyl]amino]-1-methyl-1H-pyrrole-2-carboxamide.Restriction is required under 35 U.S.C. 121 and 372.

Linking Claims

36. Claims 50-74, 78-82 and 94 link(s) inventions 1 through 34. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 50-74, 78-85 and 94. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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37. Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- 38. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The inventions listed as Groups 1 through 202 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The compounds are distinct because the structures are different. For example, 4-(Formylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4methyl-1-piperazinyl)propyllaminolcarbonyl)-1H-pyrrol-3-yllaminolcarbonyl)-1H-pyrrol-3yl]-1-methyl-1H-pyrrole-2-carboxamide is different from N²,N⁷-Bis[5-([[4-([[3-(dimethylamino)propyl]amino]carbonyl)-5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1methyl-1H-pyrrol-3-yl]-9.10-dihydro-2,7-phenanthrenedicarboxamide. Further, search for one would not lead to the other. Independent searches are required to search for the different compounds. Further, there is no common structure present. The method claims are patentably independent and distinct because of the compounds being utilized and compounds being made are structurally distinct. As described above, 4-(Formylamino)-N-[1-isopentyl-5-([[1-methyl-5-([[3-(4-methyl-1-piperazinyl)propyl]amino]carbonyl)-1Hpyrrol-3-yl]amino]carbonyl)-1H-pyrrol-3-yl]-1-methyl-1H-pyrrole-2-carboxamide is different from N².N⁷-Bis[5-([[4-([[3-(dimethylamino)propyllaminolcarbonyl)-5-isopropyl-1,3-thiazol-2-yl]amino]carbonyl)-1-methyl-1H-pyrrol-3-yl]-9,10-dihydro-2,7phenanthrenedicarboxamide. Further, search for one would not lead to the other. Independent searches are required to search for the different compounds. Further, there is no common structure present from the named compounds and search for one compound name would not necessarily lead to the other compound name. The situation involving the so-called Markush practice wherein a single claim. 39.
- defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

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40. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)
- (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (B)
- (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- 41. In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.
- 42. In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Election of Species

43. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different oligopeptide (genus);

Different nitrogen-containing basic group (genus): amidino, guandino or amino group, evelic or acvelic:

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Different heterocyclic monomers (genus): 4-12 membered group containing one or more heteroatoms N, O or S;

Different heterocyclic group (subgenus): pyrrolyl, imidazolyl, thiazolyl, oxazolyl, benzoxazolyl, furanyl, thienyl, pyridyl, or coumarinyl;

Different compounds of formula (I) due to different variables: R1, Q, n, A, D, R1a, R3a, R3b, A1, A2, R2a, R2b, R2c, R2d, R2e, R2f, R2g, R2h, R4, E, E1, E2a, E2b, E3, Het1, Het2, Het3, Het4, R5, R6, R7, R8, R9, R10, R11, G, L, p, q, r;

Different compounds of formula (II) due to different variables: R1, Het1, R1a, Q1, Q2, Q3, R2a, R2b, D, A, E, R2a, R2b, A;

Different compounds of formula (III) due to different variables: H, A, a, Aa and D;

Different compounds of formula (IV) due to different variables: R1, Q, b, Ab, and
L1;

Different compounds of formula (V) due to different variables: H, Qn, A and D;

Different compounds of formula (VI) due to different variables: L2, and E:

Different types of infections: viral, bacterial, fungal or other microbial infections (these are all subgenera).

44. Applicant is required, in reply to this action, to <u>elect a single species</u> to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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45. For any groups elected, Applicant is required to elect a single disclosed species of all of the variables of formula I or II to arrive at a single disclosed species of formula I or II compound. If a Group is elected from Group 35-67, Applicant is further required to elect a single disclose species of infection. For example, Applicant elects

Staphylococcal infection.

- 46. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
- 47. The claims are deemed to correspond to the species listed above in the following manner:

Claims 54 and 58.

The following claim(s) are generic: claims 50-53, 55-57, 59-66, 69-71 and 78-94.

48. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the oligopeptide (which is a genus) is patentably independent and distinct one from the other because the oligopeptides may have different amino acid content, leading to different structures. For example, an oligopeptide having the sequence ADVER is different than an oligopeptide having the sequence ADVER is different than an oligopeptide having the sequence ADVER is different than an oligopeptide having the sequence GHRRG. Further, search for one would not necessarily lead to the other, requiring independent searches. Different nitrogencontaining basic group (which is a genus) is patentably independent and distinct one from the other. The subgenera amidino, guanidino and amino groups claimed are also patentably independent and distinct one from each subgenus and each other. For example, a cyclic amino group has different and distinct structure than an acyclic amino group. Also, amino group has different and distinct structure than a guanidine group.

$$-\dot{C}-N \stackrel{H}{\sim}$$

while an acyclic

For example, an acyclic amino group has the structure

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amidino group has the structure NH₂. Further, search for one would not necessarily lead to the other. Further, search for a cyclic amidino group would not necessarily lead to an acyclic amidino group. Different heterocyclic group (genus) is patentably independent and distinct one from the other. For example, the subgenus pyrrolyl group

N) is patentably independent from oxazolyl group (R1

NH

). The structures are different, and search for one would not necessarily lead to the other. Therefore, an oligopeptide compound having at least one nitrogen-containing basic group and two or more heterocyclic monomers are patentably independent and distinct from each other due to different structures of the oligopeptide, nitrogen-containing basic group and heterocyclic monomers Different compounds of formula I are patentably independent and distinct because of the different variables making each compound of formula I distinct one from the other. Different compounds of formula II are patentably independent and distinct because of the different variables making each compound of formula II distinct one from the other. Different compounds of formulas III to VI are patentably independent and distinct due to the different variables associated with these formulas. For example, formula VI comprises an L2 that is a leaving group, and leaving group is a genus, since the leaving group may be anything. Formula IV also comprises an L1 that is a leaving group, and leaving group is a genus, since the leaving group may be anything. Therefore, formulas IV and VI can have many different structures, because these formulas comprise many different variables, making each structure independent and distinct from each other. The different infections are patentably independent and distinct because these infections are different from each other. For example, a virus is a small infectious organism (much smaller than fungus or bacterium) that must invade a living cell to reproduce. The viral infections include common cold. CMV infection. Dengue fever, Herpes Simplex virus infection, Influenza, etc; bacteria are microscopic, single-celled organisms. The bacterial infections include anthrax, cholera, lyme disease, plague, pseudomonas, staphylococcal infection, tetanus, etc. These infections act on different cells and have different properties and characteristics. Therefore, these infections are patentably independent and distinct.

49. Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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50. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 51. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.
- 52. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 53. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Fri. 5:30 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/ Examiner, Art Unit 1654

/Anish Gupta/ Primary Examiner, Art Unit 1654